UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,686	06/18/2001	Sandrine Segura	016800-445	9187

7590 10/15/2002

Norman H. Stepno, Esquire
BURNS, DOANE, SWECKER & MATHIS, L.L.P
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER
WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/881,686	Applicant(s) SEGURA ET AL.	
	Examiner Lauren Q Wells	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *5-7,30 and 44-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 8-29, 31-43, 47-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-50 are pending. Claims 5-7, 30 and 44-46 are withdrawn from consideration, as they are directed to non-elected subject matter. The Amendment filed 9/18/02, amended claims 41 and 42, and added claim 50.

Response to Applicant's Arguments/Amendment

The Applicant's arguments and amendment filed 9/18/02 (Paper No. 10) are sufficient-in-part to overcome the 112 rejections in the previous Office Action. See below for details.

Applicant's arguments with respect to the rejection of claims 1-49 under 35 USC 103 have been considered but are moot in view of the new ground(s) of rejection. However, to the extent that the arguments may be relevant to the present rejection, the Examiner has addressed them.

The Objection to the Oath/Declaration is maintained.

112 Rejection Maintained

The rejection of claims 1, 18, and 27 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed 8/19/02, Paper No. 8, and those found below.

(i) The phrase "said at least one biologically active agent (A) being non-solubilized therein in micronized particulate state" is still vague and indefinite. While Applicant argues, that this phrase makes it clear that the particles are not soluble in the composition, it is respectfully pointed out that from the language in the claim, it is not clear if the particles are not soluble in the emulsifying system or the composition as a whole. The Examiner respectfully suggests that Applicant change language to accurately reflect the non-solubilization of the particles in the composition as a whole.

(18) (ii) The phrase "difficultly soluble" is maintained as vague and indefinite, as the phrase "difficult to dissolve in water" in the specification does not definitely define this phrase.

(iii) The term "derivative" in claim 27 is maintained as vague and indefinite. This term encompasses an innumerable amount of compounds. The specification does not further define this term and one of ordinary skill in the art would not be apprised of the innumerable number of compounds encompassed by this term.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 8-10, 18-24, 26-29, 40-43, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. (EP 0268164) in view of Grollier et a. (6,136,332).

Lochhead et al. teach oil-in-water emulsions which contain a modified polymer which is a copolymer of an acrylic acid and a smaller amount of a long chain acrylate monomer, wherein the modified polymers function as primary emulsifiers or surfactants. The composition is disclosed as having a pH of about less than 6 is disclosed. A mixture of silicone oil and mineral oil is disclosed as comprising the oil phase. It is further disclosed that convention oil-in-water emulsions have a particle size of less than 10 microns and preferably 0.1-5 microns. The reference fails to teach an active agent. See pg. 2, line 28-pg. 14, line 10.

Grollier et al. teach dermatological/pharmaceutical compositions comprising volatile

oils/phenylated silicone oils comprising at least one bioaffecting active agent, such as antiviral, antibacterial, antifungal, anti-inflammatory, neuromediator modulator, etc. Nadifloxacin is disclosed as an antibacterial active agent for use in the composition. See Col. 2, line 35-Col. 9, line 64.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the nadifloxacin of Grollier et al. to the emulsion of Lochhead et al. because a) Grollier et al. and Lochhead et al. are both directed toward cosmetic compositions that impart skin care benefits; b) Grollier et al. teach their active agents as in composition with at least one volatile oil and Lochhead et al. teach oil-in-water emulsions comprising volatile silicone oils as constituents; c) Grollier et al. teach nadifloxacin as treating microbial infections such as acne or peribuccal impetigo and Lochhead et al teach compositions that have good cleansing effects and that open pores without being absorbed, wherein cleansing of the skin and opening pores is known to treat acne; hence, adding nadifloxacin to the compositions of Lochhead et al. would be within the skill of one in the art.

Claims 1-4, 8-29, 31-43, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (5,073,372) in view of Lochhead et al. in further view of Grollier et al., Pisson et al. (5,882,633), Kaplan (5,916,543), Klein (4,486,405) and Kim et al. (5,980,939).

Turner et al. teach leave-on facial emulsion compositions. Disclosed are oil-in-water emulsions comprising carboxylic acid copolymer, such as acrylates/C10-30 alkyl acrylate cross polymers (emulsifying system), volatile silicone oils, and carboxyvinyl polymers (gelling

agents). Waxes are further disclosed as oil phase constituents, as are pharmaceutical actives. The reference fails to teach particle size, preferred active ingredients, preferred surfactants, preferred co-surfactants, preferred wetting agents, and pH. See Col. 3, line 20-Col. 4, line 2; Col. 5, line 10-Col. 14, line 67.

Lochhead et al. is applied as discussed above.

Grollier et al. is disclosed as discussed above.

Pisson et al. teach cosmetic and/or dermatological compositions. Disclosed is an oil-in-water emulsion comprising Arlacel 165 (glyceryl and PEG-100, surfactant emulsifier), Pemulen TR1 (acrylic acid/C10-C30 alkyl acrylate, emulsifying system), and water. Oils such as cyclomethicone and co-emulsifiers are disclosed for use in the composition. See Col. 10, line 3-Col. 13, line 15.

Kaplan teaches oil-in-water emulsions having decreased skin rub-in times comprising a nonaqueous phase, an aqueous phase and an oil-in-water emulsifier. Ceteareth-20 (co-surfactant) is disclosed as a known oil-in-water emulsifier that enhances emulsion stability. See Col. 2, line 15-Col. 3, line 3.

Klein teaches a cosmetic composition comprising poloxamer 124 (wetting agent) in composition with carbomer 940 (carboxyvinyl polymer, gelling agent)) and water. See Col. 2, line 15-Col. 3, line 52; Col. 6, line 60-Col. 10, line 21.

Kim et al. teach cyclosporin containing pharmaceutical composition comprising an oil component and hydrophilic cosurfactant. Polyoxyethylene-polyoxypropylene block copolymer is disclosed as a preferred hydrophilic cosurfactant and poloxamer 124 is disclosed as the block copolymer. Poloxamer 124 is disclosed as a solubilizer for medicinal components and lipid

emulsions and as thermally stable and well disclosed in organic solvents. See Col. 6, line 27-Col. 7, line 20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Lochhead et al. into the invention of Turner et al. and obtain a water-in-oil emulsions having a particle size of 1-10 microns because a) Lochhead et al. and Turner et al. both teach oil-in-water emulsions that impart benefits to the skin; b) Lochhead et al. teach that it is conventional in the art for oil-in-water emulsions to have a particle size of less than 10 microns and preferably between 0.1 and 5 microns; hence, teaching the oil-in-water emulsion of Turner et al. as having a particle size of less than 10 microns would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nadifloxacin of Grollier et al. into the emulsion of the combined references because a) the combined references and Grollier et al. all teach cosmetic compositions that impart benefits to the skin; b) Turner et al. teach that pharmaceutical actives, such as antibiotics that induce a desired local or systemic effect can be incorporated into his emulsions, and Grollier et al. nadifloxacin as an antibacterials that imparts a local and system effect to skin care compositions; hence, the addition of nadifloxacin to the emulsion of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Arlacel 165 (surfactant emulsifier) of Pisson et al. into the emulsion of the combined references because a) Pisson et al. and the combined references both teach oil-in-water emulsions that impart benefits to the skin; b) Pisson et al. and the combined references

both teach oil-in-water emulsions comprising carboxyvinyl polymer, acrylates/C10-30 alkylacrylate cross polymer, and volatile silicone oils; c) Pisson et al. additionally teach Arlacel 165 in their emulsion; hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add Arlacel 165 to the composition of the combined references because Pisson and the combined references both teach acrylates/C10-30 alkylacrylate cross polymer emulsifying systems and Pisson teaches Arlacel 165 as a surfactant emulsifier in such a system, and because of the expectation of increasing the solubility of constituents in the composition and of increasing the stability of the oil-in-water emulsion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the ceteareth-20 (co-surfactant) of Kaplan to the emulsion of the combined references because a) the combined references and Kaplan all teach oil-in-water cosmetic emulsions that impart skin care benefits; b) the combined references teach emulsions comprising co-surfactants such as glyceryl monohydroxy stearate and Kaplan et al. teach ceteareth-20 and glycerol monostearate as interchangeable and combinable co-surfactants; c) Kaplan et al. also teach that mixtures of emulsifiers (surfactants) are frequently desirable for enhancing emulsion stability; hence, the substitution of ceteareth-20 for glyceryl monohydroxy stearate in the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the poloxamer 124 (wetting agent) of Klein into the emulsion of the combined references because a) the combined references and Klein all teach cosmetic compositions; b) Klein exemplifies compositions comprising poloxamer 124, water and carbomer (carboxyvinyl polymer) and Turner et al. teach their composition as comprising water and carbomer; c) Kim et

al. teach poloxamer 124 as a surfactant that is useful as a solubilizer for medicinal components and lipid emulsions, as being thermally stable, and as being well dissolved in organic solvents; hence, one of skill in the art would be have been motivated to add poloxamer 124 to the composition of the combined references because of the expectation of further solubilizing the active agents and of increasing thermal stability.

Claims 1-4, 8-29, 31-43, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (5,750,122) in view of Lochhead et al. in further view of Grollier et al., Pisson et al., Klein, and Kim et al.

Evans et al. teach compositions for treating hair or skin. Disclosed is an anti-acne oil-in-water emulsion comprising water, glycerin, carbomer (carboxyvinyl polymer, gelling agent), acryaltes/c10-30 alkylacrylates crosspolymer (emulsifying system), stearyl alcohol, cetyl alcohol and PEG-4. Volatile silicone agents are disclosed as conditioning agents for use in the composition. The reference fails to teach particle size, preferred active ingredients, preferred surfactant, preferred co-surfactant, and preferred wetting agent. See Col. 2, line 17-Col. 17, line 20.

Lochhead et al. is applied as discussed above.

Grollier et al. is disclosed as discussed above.

Pisson et al. is applied as discussed above.

Klein is applied as discussed above.

Kim et al. is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Lochhead et al. into the invention of Evans et al. and

obtain a water-in-oil emulsions having a particle size of 1-10 microns because a) Lochhead et al. and Evans et al. both teach oil-in-water emulsions that impart benefits to the skin; b) Lochhead et al. teach that it is conventional in the art for oil-in-water emulsions to have a particle size of less than 10 microns and preferably between 0.1 and 5 microns; hence, teaching the oil-in-water emulsion of Evans et al. as having a particle size of less than 10 microns would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nadifloxacin of Grollier et al. into the emulsion of the combined references because a) the combined references and Grollier et al. all teach cosmetic compositions that impart benefits to the skin; b) Evans et al. teach that antimicrobial agents and anti-acne agents can be added to their emulsion, and Grollier et al. nadifloxacin as an antibacterial, anti-acne agent for use in skin care compositions; hence, the addition of nadifloxacin to the emulsion of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Arlacel 165 of Pisson et al. into the emulsion of the combined references because a) Pisson et al. and the combined references both teach oil-in-water emulsions that impart benefits to the skin; b) Pisson et al. and the combined references teach oil-in-water emulsions comprising carboxyvinyl polymer, acrylates/C10-30 alkylacrylate cross polymer, and volatile silicone oils; c) Pisson et al. additionally teach Arlacel 165 in their emulsion; thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add Arlacel 165 to the composition of the combined references because Pisson and the combined references both teach acrylates/C10-30 alkylacrylate cross polymer emulsifying systems and

Pisson teaches Arlacel 165 as a surfactant emulsifier in such a system, and because of the expectation of increasing the solubility of constituents in the composition and of increasing the stability of the oil-in-water emulsion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the poloxamer 124 (co-surfactant) of Klein into the emulsion of the combined references because a) the combined references and Klein all teach cosmetic compositions; b) Klein exemplifies compositions comprising poloxamer 124, water and carbomer (carboxyvinyl polymer) and Evans et al. teach their composition as comprising water and carbomer; c) Kim et al. teach poloxamer 124 as a surfactant that is useful as a solubilizer for medicinal components and lipid emulsions, as being thermally stable, and as being well dissolved in organic solvents; hence, one of skill in the art would be have been motivated to add poloxamer 124 to the composition of the combined references because of the expectation of further solubilizing the active agents and of increasing thermal stability.

Claims 1-4, 8-29, 31-43, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisson et al. in view of Lochhead et al. in further view of Grollier et al., Kaplan, Klein, and Kim et al.

Pisson et al. is applied as discussed above. The reference fails to teach particle size, preferred active agents, preferred co-surfactants, preferred wetting agents, preferred gelling agents, and pH.

Lochhead et al. is applied as discussed above.

Grollier et al. is applied as discussed above.

Kaplan is applied as discussed above.

Klein is applied as discussed above.

Kim is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Lochhead et al. into the invention of Pisson et al. and obtain a water-in-oil emulsions having a particle size of 1-10 microns because a) Lochhead et al. and Pisson et al. both teach oil-in-water emulsions that impart benefits to the skin; b) Lochhead et al. teach that it is conventional in the art for oil-in-water emulsions to have a particle size of less than 10 microns and preferably between 0.1 and 5 microns; hence, teaching the oil-in-water emulsion of Evans et al. as having a particle size of less than 10 microns would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the nadifloxacin of Grollier et al. into the emulsion of the combined references because a) the combined references and Grollier et al. all teach cosmetic compositions that impart benefits to the skin; b) Pisson et al. teach typical additives and adjuvants in the cosmetics field that impart benefit to the skin can be added to their emulsion, and Grollier et al. nadifloxacin as an antibacterial, anti-acne agent for use in skin care compositions; hence, the addition of nadifloxacin to the emulsion of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the ceteareth-20 of Kaplan to the emulsion of the combined references because a) the combined references and Kaplan all teach oil-in-water cosmetic emulsions that impart skin care benefits; b) the combined references teach emulsions comprising surfactants, such as

glyceryl monostearate and polyethylene glycol stearate mixture, and co-surfactants, and Kaplan teaches ceteareth-20, glyceryl monostearate, and polyethylene glycol stearate as interchangeable and combinable surfactants; c) Kaplan also teaches that mixtures of emulsifiers (surfactants) are frequently desirable for enhancing emulsion stability; hence, the substituting ceteareth-20 for the glyceryl monostearate of the combined references for cosmetic purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the poloxamer 124 of Klein into the emulsion of the combined references because a) the combined references and Klein all teach cosmetic compositions; b) Kim et al. teach poloxamer 124 as a surfactant that is useful as a solubilizer for medicinal components and lipid emulsions, as being thermally stable, and as being well dissolved in organic solvents; hence, one of skill in the art would be have been motivated to add poloxamer 124 to the composition of the combined references because of the expectation of further solubilizing the active agents and of increasing thermal stability.

Response to 103 Arguments

Applicant argues, "Lockhead and Grollier are incompatible. . .Lockhead pertains to oil-in-water emulsions, whereas the compositions of Grollier are substantially non-aqueous". This argument is not persuasive. The Examiner respectfully points out that the Examiner has not attempted to bodily incorporate the composition of Grollier into that of Lockhead, but has incorporated an active agent soluble in an oil phase of Grollier into the oil phase of Lockhead. As stated in the previous Office Action, both Grollier and Lockhead are directed toward cosmetic compositions that impart skin care benefits; Grollier teach their active agents as in

composition with at least one volatile oil and Lockhead teach oil-in-water emulsion comprising volatile silicone oils; Grollier et al. teach nadifloxacin as treating microbial infections such as acne or peribuccal impetigo and Lockhead teaches compositions that have good cleansing effects and that open pores without being absorbed, wherein cleansing the skin and opening pores is known to treat acne; hence, adding nadifloxacin to the compositions of Lockhead et al. would be within the skill of one in the art.

Applicant argues, "Neither Lockhead nor Grollier provide these non-solubilization, micronization and size limitations of Applicants' claimed invention". This argument is not persuasive. The Examiner respectfully points out that on page 8 of Lochhead, teaches that the particles of his oil-in-water emulsion are in the range of 10-100microns and that oil-in-water emulsions having a particle size of less than 10microns are conventional in the art.

Applicant argues, "The emulsions of Turner are of the oil-in-water type, and thus are as incompatible with Grollier as were the emulsions of Lockhead". This argument is not persuasive. The Examiner respectfully points out that the Examiner has not attempted to bodily incorporate the composition of Grollier into that of Turner, but has incorporated an active agent soluble in an oil phase of Grollier into the oil phase of Turner. See above for the explicit motivation to combine them.

Applicant argues, regarding Turner, "Applicants claimed invention does not require such a cationic surfactant". This argument is not persuasive, as the term "comprising" in the instant claims, is open-ended, and therefore does not exclude any ingredients from the instant composition.

In the instant response, Applicant has argued against the references individually. The

Examiner respectfully points out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). However, to the extent that the arguments may be relevant to the rejection, the Examiner has addressed them.

Applicant argues, "The compositions of Pisson require three essential elements which are not required by Applicants' compositions. Moreover, the compositions of Pisson do not contain a biologically active agent, whereas such an agent is essential to Applicants compositions". This argument is not persuasive. First, the Examiner respectfully points out that the instant claims recite the term "comprising" as their transitional phrase, thereby not excluding any ingredients from their composition. Second, the Examiner respectfully points out that Pisson was not relied upon to teach a biologically active agent.

Applicant argues, "The emulsions of Kaplan do not contain biologically active agents, as do Applicants' compositions. In addition, Kaplan is silent as to the use of an emulsifying system comprising carboxylic acid copolymers". This argument is not persuasive. The Examiner respectfully points out that Kaplan was not relied upon for teaching biologically active agents or an emulsifying system.

Applicant argues, "The compositions of Klein are aqueous, and thus incompatible with Grollier. The compositions of Klein do not contain biologically active agents, as do Applicants' compositions, nor do the compositions of Klein contain the essential elements of the other cited publications". This argument is not persuasive. First, the Examiner respectfully points out that Klein and Grollier were not explicitly combined, but that Klein was combined with "combined

references". For the reasons stated above, it was obvious to combine the teachings of Grollier with that of the primary reference. Second, the Examiner respectfully points out that Klein was not relied upon for teaching biologically active agents, and it is not known what Applicant means by "nor do the compositions of Klein contain the essential elements of the other cited publications".

Applicant argues, "Applicants' compositions, like the compositions of Lockhead, Grollier, Turner, Pisson, Kaplan and Klein, fail to contain all four Kim essential elements. This goes against combining Kim as suggested by the Examiner". This argument is not persuasive, as Kim is merely relied upon to teach conventional properties of a surfactant, poloxamer 124.

Applicant argues, "Evans pertains to compositions useful for treating hair or skin, and contain panthenol and at least one polyalkylene glycol. . .The compositions of Lockhead, Grollier, Pisson, Klein, and Kim do not require panthenol and polyalkylene glycol—making the combination of these publications impermissible". This argument is not persuasive. First, the Examiner respectfully points out that the cited references are directed to compositions that are useful for treating hair. Second, the Examiner respectfully points out the instant claims recite the term "comprising" as their transitional phrase, thereby not excluding any ingredients from their composition.

Applicant argues, "Notably, the compositions of Pisson contain three essential elements which are lacking in the cited publications, making impermissible such a combination". This argument is not persuasive. Again, the Examiner respectfully points out the instant claims recite the term "comprising" as their transitional phrase, thereby not excluding any ingredients from their composition.

Applicant argues, "Applicants' invention may not be used as a template for assembling an invention". This argument is not persuasive, as it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
October 9, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER 10/14/02